REMARKS

Claims 1, 3-17, 19-24, 27-33, and 35-42 are pending in this application.

Claim 1 has been amended to incorporate the subject matter previously recited in claim 2. As a result, claim 2 has been cancelled. Various claims which previously depended from claim 2 have also been amended and now depend from claim 1. Claim 18 has been cancelled in response to the Examiner's objection and because it appears to be superfluous in view of amendments previously made to claim 1. The claims which depended from claim 18 have been amended so that they now depend from claim 1.

It is respectfully submitted that no new matter has been added by virtue of these amendments.

Objection to claim 18 under 37 CFR 1.75(c)

In the Office Action, the Examiner objected to claim 18 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. As this claim has been canceled, the present rejection is moot.

§ 102(b) as being anticipated by and 35 U.S.C. § 103(a) as being unpatentable over Curtet

In the Office Action, the Examiner rejected claims 1, 16-24, 27, 29-32, and 41-42 under 35 U.S.C. § 102(b) as being anticipated by Curtet et al. (U.S. Patent No. 4,895,726) (hereinafter "the Curtet patent"). The Examiner also rejected claims 1, 7-12, 16-24, 27, 29-32, 35-36, and 39-42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Curtet.

Claim 1 as amended, recites:

> A method for making composite active particles for pulmonary inhalation, the method comprising the step of jet milling active particles in the presence of particles of additive material so that the additive material coats the active particles, wherein the additive material is selected from the group consisting of: an amino acid, a metal stearate and a phospholipid.

Claim 1 has been amended to incorporate the subject matter of claim 2. Claim 2 was not rejected by the Examiner as either anticipated or obvious in view of the Curtet patent. Therefore, Applicant respectfully requests withdrawal of the present rejection of claim 1. As the remainder of the claims depend directly or indirectly depend from claim 1, withdrawal of the rejection of these claims is also respectfully requested.

Notwithstanding the above, Applicants point out that the Curtet patent does not disclose or suggest composite active particles formed by jet milling active particles in the presence of particles comprising an amino acid, a metal sulphate or a phospholipid. This is acknowledged by the Examiner e.g. on page 9 of the present Office Action when he confirms that "Curtet lacks the teaching of a method utilizing lecithin as a co-jet milled additive". Therefore, the present claims, which include this subject matter, cannot be anticipated by the Curtet patent.

Turning to inventive step, Applicants again point out that the Curtet patent is only directed to oral formulations and does teach or suggest the use of its composite active particles for pulmonary inhalation. The Curtet patent is purportedly directed to an oral dosage form of fenofibrate formulated by co-micronising the fenofibrate with a solid surfactant. According to the Curtet patent, when an oral dosage form of fenofibrate is created this way the bioavailability of the active agent is increased (when taken orally) when compared with a nonmicronised formulation.

However, one skilled in the art at the time of the invention would have been well aware that oral routes of administration are absorbed in a very different manner than nasal or pulmonary inhalation products. The physical properties are also very different, as a product that may be swallowed and easily released in the gastrointestinal tract may not be suitable for inhalation. For example, if not formulated properly, a formulation for pulmonary inhalation may not be properly expelled from the inhalation device or may be dumped into the patient's mouth rather than entering the patient's airway. Therefore, one of skill would not consider the teaching of the Curtet patent when attempting to improve upon known dry powder formulations for administration by pulmonary inhalation. As a result, the Curtet patent, which is only directed to oral dosage forms, cannot render claims directed to pulmonary inhalation obvious.

Further, the Curtet patent describes the effect of co-micronising fenofibrate with a solid surfactant, namely sodium lauryl sulphate but does not explain how or why a beneficial effect is achieved, nor does it disclose or suggest that other alternative materials could be co-micronised with the active agent to achieve a similar effect. Therefore, it would not be obvious to one of skill in the art to replace the surfactant used by Curtet et al with an alternative additive material selected from the group consisting of an amino acid, a metal stearate and a phospholipids, let alone to use that altered formulation in a composition for pulmonary inhalation..

In view of the above, Applicant submits that the pending claims are not rendered obvious in view of the Curtet patent. Withdrawal of the rejection is therefore respectfully requested.

35 U.S.C. § 103(a) as being unpatentable over Curtet in view of Hochschild

Claims 2 and 6 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Curtet patent (U.S. Patent No. 4,895,726) as applied to claims 1, 7-12, 16-24, 27, 29-32, 35-36, and 39-42 above, and further in view of Hochschild (U.S. Patent No. 4,374,082).

As explained above, the Curtet patent does not disclose or suggest composite active particles formed by jet milling active particles in the presence of particles comprising an amino acid, a metal sulphate or a phospholipids and is directed only to oral formulations and does teach or suggest the use of its composite active particles for pulmonary inhalation.

The Hochschild patent does not cure the deficiencies of the Curtet patent as it also is only directed to oral formulations and does not disclose or suggest the use of its formulations for pulmonary inhalation. As discussed above, one skilled in the art at the time of the invention would have been well aware that oral routes of administration are absorbed in a very different manner than nasal or pulmonary inhalation products. The physical properties are also very different, as a product that may be swallowed and easily released in the gastrointestinal tract may not be suitable for inhalation. One of skill, combining the teachings of the Curtet and Hochschild patent therefore would still not achieve a formulation for pulmonary inhalation, only one for oral administration.

"[T]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. KSR International Co. v. Teleflex Inc., 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007)" MPEP Section 2143.01. In the present situation, the results of a suitable method for pulmonary inhalation would not have been predictable from the teachings of two patents relating to oral formulations.

Further, the Examiner has provided no reason for why one of skill in the art would look to combine the Hochschild patent with the Curtet patent. The Hochschild patent contemplates a very different process for manufacturing solid dosage forms for oral administration is used. Specifically, the Hochschild patent uses lecithin, in combination with the active agent, to produce a dough which may be extruded and formed into individual dosage forms. This is very different from the manufacturing process disclosed by Curtet patent.

As stated by the Board of Patent Appeals and Interferences in Appeal No. 2007-4423, Decision of Appeal dated July 23, 2008:

> obviousness cannot be proven merely by showing that the elements of a claimed device were known in a prior art; it must be shown that those of ordinary skill in the art would have had some "apparent reason to combine the known elements in the fashion claimed ...
>
> [Similarly,] obviousness cannot be proven merely by showing that a known composition have could have been modified by routine experimentation or solely on the expectation of success; it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that result in the claimed composition.

In the present situation, neither of the cited patents discloses or suggests a formulation for pulmonary inhalation. No reason has been shown for why one of skill in the art would combine the separate elements of the different processes of the Curtet patent and the Hochschild patent. No reason has been shown for why one of skill in the art would modify the composition of Curtet

in view of the teaching of the Hochschild patent in a way to result in the claimed method for making composite active particles for pulmonary inhalation.

Applicants therefore submit that claims 2 and 6 are not obvious under 35 U.S.C. 103(a) over the Curtet patent as applied to claims 1, 7-12, 16-24, 27, 29-32, 35-36, and 39-42 above, and further in view of Hochschild (U.S. Patent No. 4,374,082). Withdrawal of this rejection is respectfully requested.

Double patenting rejections

Claims 1, 5-8, 11-12, 16-20, 23-24, 27, and 35 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 16-19, and 21- 22 of U.S. Patent No. 7,736,670.

Applicants respond that the filing of a terminal disclaimer will be considered upon notification that the pending claims are otherwise allowable.

Claims 1-2, 5-8, 11-12, 16-24, 27, 35-36, and 39-40 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20, 33-35, 37, 39, 42-43, and 59-61 of copending Application No. 10/433,185.

Applicants respond that the filing of a terminal disclaimer will be considered upon notification that the pending claims are otherwise allowable.

Claims 1-2, 5, 7-8, 11-12, 16-17, 21-22, 27, 29-33, 35, and 41-42 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 10/552,326.

Applicants respond that the filing of a terminal disclaimer will be considered upon notification that the pending claims are otherwise allowable.

Claims 1, 7-8, 11-16, 28, and 35-38 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-9, and 26 of copending Application No. 11/791,385.

Applicants respond that the filing of a terminal disclaimer will be considered upon notification that the pending claims are otherwise allowable.

Claims 1-12, 16-24, 29-32, 35-36, and 39-42 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6, 12, 15-22, 26, 30, and 39-40 of copending Application No. 11/791,670.

Applicants respond that the filing of a terminal disclaimer will be considered upon notification that the pending claims are otherwise allowable.

Claims 16-18, 21-24, and 27-33 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35, 38, 41-43, and 45 of copending Application No. 12/767,530.

Applicants respond that the filing of a terminal disclaimer will be considered upon notification that the pending claims are otherwise allowable.

CONCLUSION

Reconsideration of the present application is requested. This Response is being submitted in response to the Office Action dated October 12, 2010 in the above-identified application. Concurrently with this Response, Applicant submits a petition for a three-month extension of time for filing a response, along with the requisite fee. If it is determined that any additional fee is due in connection with this filing, the Commissioner is authorized to charge said fees to Deposit Account No. 50-0552.

An early and favorable action on the merits is earnestly requested.

Respectfully Submitted,
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